DECLARATION OF ALLEN S. KESSELRING, Ph.D.

1. I, Allen S. Kesselring, Ph.D., have studied and worked within the fields of medicinal drug discovery, organic synthesis and analytical chemistry for over 20 years. I am currently employed at E.KG. Life Science Solutions. Attached to this declaration as "Kesselring Exhibit A" is a copy of my *curriculum vitae*, which further details my training and experience.

2. Beginning in 2005, I have routinely worked with controlled substances (schedules I-V) in the development and/or validation of methods for the identification and/or quantification of such materials. My training and background in organic chemistry and structural analysis provide me with the necessary expertise to opine on matters that involve the structural identification of controlled substances and/or analogues thereof.

3. I have reviewed a document within Exhibit 2-I entitled "Affidavit in Support of Application for Search Warrant" (NC 00015214 – NC 00015292) that was attached to an Application for a Search Warrant for 4738 Orchard Drive, Barnhart, MO 63012 sworn by Wayne House, Special Agent, Immigration and Customs Enforcement, Homeland Security Investigations on September 24, 2013 in Case No. 4:13MJ07227 SPM (NC 00015209 - NC00015213) (the "Orchard Drive Affidavit").

4. Paragraph 13 of the Orchard Drive Affidavit excerpts part of the definition of "controlled substance analogue" from Title 21 U.S.C. § 802(32)(A), including subpart (i): "the chemical structure of which is *substantially similar* to the chemical structure of a controlled substance in schedule I or II." Definitions ordinarily establish and detail criteria by which it can be determined whether something meets the criteria and therefore falls within the definition. There is however no established scientific definition nor recognized scientific criteria to determine whether one chemical structure is "substantially similar" to another. In order to credibly opine that a chemical's structure is substantially similar to that of another chemical, it

should nevertheless be expected that the person offering the opinion has a significant level of training and expertise in organic chemistry and molecular structure identification in order to render such a highly subjective expert comparison.

5. The Synthetic Drug Abuse Prevention Act of 2012 ("SDAPA") amended Title 21 U.S.C. and included definitions for five structural classes of "Cannabimimetic Agents". The five Cannabimimetic Agent structural class definitions, present in Title 21, U.S.C. § 812, utilize standard scientific nomenclature, which does not require subjective interpretation. Under Title 21, U.S.C. § 812:

> [t]he term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:
>
> (i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.
>
> (ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.
>
> (iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

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(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

6. Paragraph 21 of the Orchard Drive Affidavit states that AKB48 and 5F-AKB48 "are *structurally related* to other synthetic cannabinoids with a core indole structure, such as Schedule I substances JWH-018 and AM2201. These core structures (scaffolds) are substituted at the 1- and 3-positions." This statement is, at minimum, misleading because JWH-018 and AM2201 fall within a specific recognized structural class of Cannabimimetic Agents under Title 21, U.S.C. § 812 and the materials AKB48 and 5F-AKB48 which have indazole cores, do <u>not</u> fall within any of the defined structural classes of Cannabimimetic Agents.

7. Moreover, the term "structurally related" used in Paragraph 21 of the Orchard Drive Affidavit is not a term that is defined, nor does it have precise scientific meaning. If the Affidavit intends to suggest that the "structural relationship" it claims AKB48 and 5F-AKB48 to have with other synthetic cannabinoids such as Schedule I substances JWH-018 and AM2201 renders AKB48 and 5F-AKB48 to be controlled substance analogues of JWH-018 and AM2201 within the definition of analogue under Title 21 U.S.C. § 802(32)(A)(i), then that assertion of Paragraph 21 of the Affidavit is false. To conclude that AKB48 and 5F-AKB48 are controlled substance analogues of JWH-018 and AM2201 on that basis would be to say that "structurally related" is sufficient to meet the § 802(32)(A)(i) criteria of "substantially similar to". If this were scientifically true (which it is not), then the common and essential amino acid tryptophan,

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having structural relation to several schedule I controlled substances, could be considered a controlled substance analog on the same basis (which it is not).

8. Further, while paragraph 21 of the Orchard Drive Affidavit asserts that "AKB48 is *pharmacologically similar* to Schedule I substances THC and various synthetic cannabinoids (e.g. JWH-018, AM2201 etc.)", no scientific evidence is presented to support such a claim, nor is any reference made to a study that substantiates such an assertion. Even if claims about the *in vitro* pharmacologic activity of AKB48 were found to be true, there is no evidence presented in to support a conclusion that 5F-AKB48 would have similar pharmacologic activity to THC or any synthetic cannabinoid. It is furthermore noted that a person who does not have formal education and training in medicinal chemistry, biochemistry, or pharmacology would not have sufficient knowledge or understanding to reach that conclusion, one that is not scientifically justified.

9. Paragraph 22 of the Orchard Drive Affidavit states that "AB-PINICA and AB-FUBINACA are cannabimimetic indazole-derivatives". This too is, at a minimum, a misleading statement. Neither AB-PINICA nor AB-FUBINACA falls within any of the five classes of compounds that are formally defined as Cannabimimetic Agents in Title 21, U.S.C. § 812.

10. Paragraph 36(a) of the Orchard Drive Affidavit provides no basis to support the assertion that AKB48 N-(5-fluoropentyl), also known as (N-((3s,5s,7s)-adamantan-l-yl)-l-(5-fluoropentyl)-iH-indazole-3-carboxamide also known as 5F-AKB48, meets criteria of "a synthetic cannabinoid controlled substance analog per DEA control # 7201". DEA control # 7201 is that of the material known as AM2201. As previously noted, the structure of AM2201 falls within one of the five classes of Cannabimimetic Agents defined in 21 U.S.C. § 812. Also as previously noted, 5F-AKB48, having an indazole core, does <u>not</u> fall within any of the

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structural classes of Cannabimimetic Agents defined in 21 U.S.C. § 812. Furthermore, the presence of the "N-((3s,5s,7s)-adamantan-l-yl)" functionality in 5F-AKB48 continues to render it distinct from AM2201 insofar as 5F-AKB48 is an "alkyl amide" and AM2201 is an "aryl ketone". Agent House's assertion that 5F-AKB48 is a controlled substance analogue of AM2201 is incorrect as they share neither a core structural class, nor predominate structural functionality.

11. It is notable that substantial portions of paragraphs 16 to 21 of the Orchard Drive Affidavit appear to be drawn from sources that Agent House does not cite and which presumably he did not author. I believe this to be the case because by conducting internet searches, I found text of documents that closely matched the text of the affidavit, but none of the documents that returned on those searches were authored by Agent House. Furthermore, the replicated text does not contain material that it references and relies upon to reach the conclusions it does. This is clearly shown in paragraph 21 where "(R1 and R2, respectively)" references material which is not present in the Orchard Drive Affidavit. R1 and R2 have no independent significance without a related structural illustration of the corresponding substitution positions of each term. The affidavit contains no material that establishes where R1 and R2 are found on any corresponding illustration, or the significance of those positions to the conclusion the affidavit reaches. The use of the R1 and R2 references in the affidavit appears to be a careless replication of text from an uncited source that omits the corresponding structural illustration and therefore provides no basis for the related conclusions. In order to take the related assertions as true, the reader would therefore have to make assumptions regarding the substitution positions of R1 and R2, which are not found in the affidavit.

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12. A person who does not have formal education and training in organic chemistry, molecular structure and biochemistry would not have sufficient knowledge or understanding to reach the scientific conclusions set forth in paragraphs 16 to 21 of the Orchard Drive Affidavit.

13. I have reviewed a document within Exhibit 5-B entitled "Affidavit in Support of Application for Search Warrant" (NC 00014774 – NC 00014806) that was attached to an Application for a Search Warrant for the email account bearing the address of rkwolfe1971@yahoo.com sworn by Robert J. Anderson, Special Agent Internal Revenue Service Criminal Investigative Division on January 10, 2014 in Case No. 4:13 MJ 07002 SPM (NC 00014773)(the "Yahoo Email Affidavit").

14. Paragraph 24 of the Yahoo Email Affidavit is states that AKB48 and 5F-AKB48 "are *structurally related* to other synthetic cannabinoids with a core indole structure, such as Schedule I substances JWH-018 and AM2201. These core structures (scaffolds) are substituted at the 1- and 3-positions (R1 and R2, respectively)." This statement is, at minimum, misleading because JWH-018 and AM2201 fall within a specific recognized structural class of Cannabimimetic Agents under Title 21, U.S.C. § 812 and the materials AKB48 and 5F-AKB48 which have indazole cores, do <u>not</u> fall within any of the defined structural classes of Cannabimimetic Agents.

15. Paragraph 24 and 25 of the Yahoo Email Affidavit each reference "R1 and R2, respectively". R1 and R2 have no independent significance without a related structural illustration of the corresponding substitution positions of each term. The affidavit contains no material that establishes where R1 and R2 are found on any corresponding illustration, or the significance of those positions to the conclusion the affidavit reaches. The use of the R1 and R2 references in the affidavit appears to be a careless replication of text from an uncited source that

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omits the corresponding structural illustration and therefore provides no basis for the related conclusions. In order to take the related assertions as true, the reader would therefore have to make assumptions regarding the substitution positions of R1 and R2, which are not found in the affidavit.

16. Paragraph 25 of the Yahoo Email Affidavit repeatedly makes reference to "5F-UR144 and XLR11" in context which assumes they are two unique compounds, when in fact, they are the same compound. The conclusion statement's mixture of numerical reference "XLR11 is (single compound) a schedule I controlled substances (plural) under the Federal Controlled Substances Act" highlights the confusion brought on by what is assumed to be careless replication of text.

17. Paragraph 26 of the Yahoo Email Affidavit suggests "AB-PINICA and AB-FUBINACA are cannabimimetic indazole-derivatives". This is, at a minimum, a misleading statement. Neither AB-PINICA nor AB-FUBINACA falls within any of the five classes of compounds that are formally defined as Cannabimimetic Agents in Title 21, U.S.C. § 812.

18. I have reviewed a document within Exhibit 9 entitled "Affidavit in Support of Application for Search Warrant" (NC 00015297 – NC 00015325) that was attached to an Application for a Search Warrant for 21 Winding Stairway, O'Fallon, MO 63368 sworn by Wayne House, Special Agent, Immigration and Customs Enforcement, Homeland Security Investigations on June 6, 2014 in Case No. 4:13MJ07227 SPM (NC 00015293 - NC00015296) (the "Winding Stairway Affidavit").

19. Paragraph 13 of the Winding Stairway Affidavit states that AKB48 and 5F-AKB48 "are *structurally related* to other synthetic cannabinoids with a core indole structure, such as Schedule I substances JWH-018 and AM2201. These core structures (scaffolds) are

substituted at the 1- and 3-positions (R1 and R2, respectively)". This statement is, at minimum, misleading because JWH-018 and AM2201 fall within a specific recognized structural class of Cannabimimetic Agents under Title 21, U.S.C. § 812 and the materials AKB48 and 5F-AKB48 which have indazole cores, do not fall within any of the defined structural classes of Cannabimimetic Agents.

20. Paragraph 13 of the Winding Stairway Affidavit suggests evaluation of positions "R1 and R2, respectively". R1 and R2 have no independent significance without a related structural illustration of the corresponding substitution positions of each term. The affidavit contains no material that establishes where R1 and R2 are found on any corresponding illustration, or the significance of those positions to the conclusion the affidavit reaches. The use of the R1 and R2 references in the affidavit appears to be a careless replication of text from an uncited source that omits the corresponding structural illustration and therefore provides no basis for the related conclusions. In order to take the related assertions as true, the reader would therefore have to make assumptions regarding the substitution positions of R1 and R2, which are not found in the affidavit.

21. Paragraph 14 of the Winding Stairway Affidavit discusses substances referred to as PB-22 and 5F-PB-22 and states that along with JWH018 and AM2201, they belong to a structural class of substances that share a core indole structure. Paragraph 14 concludes based on unnamed, undisclosed studies that PB-22 and 5F-PB-22 "are expected to have similar effects" as JWH-018. It is meaningful to note the repeated gaps in scientific position that paragraph 14 requests the reader to cross and accept without evidence. After making unsubstantiated claims associated with animal behavior studies involving JWH018, the reader is asked to extend those claims, without evidence, to the *in vivo* pharmacologic activity of JWH018. The reader is then

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asked to project the supposed *in vivo* activity of JWH018 unto PB-22 and 5F-PB-22, again without evidence. There is no is no evidence presented that PB-22 or 5F-PB-22 would have similar pharmacologic activity to THC or any synthetic cannabinoid. Is furthermore noted that a person who does not have formal education and training in medicinal chemistry, biochemistry, or pharmacology would not have sufficient knowledge or understanding to reach that conclusion, one that is presented in the Winding Stairway Affidavit without scientific justification.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 07, 2016

Allen S. Kesselring, Ph.D.

Exhibit 12

CURRICULUM VITAE

Allen Kesselring, PH.D.

Educational Background

PH.D. ORGANIC CHEMISTRY
Washington University, Saint Louis, MO
January 2006

A.M. ORGANIC CHEMISTRY
Washington University, Saint Louis, MO
August 2002

B.S. CHEMISTRY AND MATHEMATICS
Missouri Baptist University, Creve Coeur, MO
May 2000

Research and/or Scientific Experience

CHIEF SCIENCE OFFICER
E.K.G. Life Science Solutions, Saint Louis, MO
April 2013 – Present

MANAGING DIRECTOR
EAG Life Sciences, Maryland Heights, MO
January 2012 – April 2013

VICE PRESIDENT AND GENERAL MANAGER
EAG Life Sciences, Maryland Heights, MO
Formerly Cyanta Analytical Services, Maryland Heights, MO
November 2010 – January 2012

DIRECTOR OF ANALYTICAL OPERATIONS
Cyanta Analytical Services, Maryland Heights, MO
February 2010 – November 2010

LABORATORY MANAGER
Cyanta Analytical Laboratories, Maryland Heights, MO
(formerly: Azopharma Contract Pharmaceutical Services and Chemir Analytical Services)
October 2006 – February 2010

SENIOR ANALYTICAL CHEMIST
Chemir Analytical Services, Maryland Heights, MO
September 2005 – October 2006

Kesselring Exhibit "A"

CURRICULUM VITAE

Allen Kesselring

Research and/or Scientific Experience

GRADUATE RESEARCH ASSISTANT
Washington University, Saint Louis, MO
August 2000 - September 2005

RESEARCH INTERN
Pfizer (formerly Pharmacia and Monsanto) Saint Louis, MO
Summers 1997 - 2000

Publications and Presentations

"Examining th e Growing Challenges of Extractables and Leachables" Sutton, Stephanie; Christiaen, Piet; Feiden, Andrew; Kesselring, Allen; Killian, Paul; Rushing, Wayland; Invited Industry Expert; Pharmaceutical Technology, 38 (2012)

"Quantitative Determination of Extractables and Leachables within a Nebulized Product Container Closure System by GC/MS" Kesselring, Allen S.; 2012 AAPS Annual Meeting & Exposition; Chicago, IL; October 14–18, 2012

"Method Development and GLP Validation for the Quantitative Determination of Oxymetazoline in Rat Plasma using LC/MS/MS" Kesselring, Allen S.; 2012 AAPS Annual Meeting & Exposition; Chicago, IL; October 14–18, 2012

"Robust Analytical Methods for Genotoxic Impurities" Currin, Lloyd, Kesselring, Allen; PharmTech.com, White Paper Article; September 25, 2012

"Extractables and Leachables for Pharmaceuticals and Medical Devices" Kesselring, Allen; PharmTech.com, White Paper Article; July 31, 2012

"Chemical Characterization of Medical Devices". Kesselring, Allen S., Presenter, Medical Device Development and the Role of Physical & Chemical Testing: Exploring Device Development Pitfalls and Failures, San Francisco, CA; May 11, 2011 and Boston, MA; September 13, 2011

"Parallel Solid-Phase Synthesis and High-Throughput 1H NMR Evaluation of a 96-Member 1,2,4-Trisubstituted-pyrimidin-6-one-5-carboxylic Acid Library", Hamper, Bruce; Kesselring, Allen S.; Chott, Robert C.; Yang, Shengtian, J. Comb. Chem., 11(3),469-480, (2009)

"Solid-Phase Synthesis of Di-β-Peptoids from Acrylate Resin: *N*-Acetyl-*N*-Benzyl-β-Alaninyl-*N*-Benzyl-β-Alanine", Hamper, Bruce C.; Kesselring, Allen S.; Parker, Marshall; Turner James A., Solid-Phase Organic Syntheses, 1, 55, (2001)

Kesselring Exhibit "A"

Allen Kesselring

Publications and Presentations

"Tungsten alkyne-ol cyclizations with aldehydes to form biologically interesting molecules". Kesselring, Allen S.; Gilbertson, Scott R. Abstracts of Papers, 228th ACS National Meeting, Philadelphia, P A, United States, August 22-26, 2004

"God and Science" Allen S. Kesselring. Invited lecturer to Missouri Baptist; University Donor Luncheon. Spring 2001

"Parallel solid-phase synthesis and high-throughput 1H NMR evaluation of a 96-member 1A-trisubstituted-pyrimidin-6-one-5-carboxylic acid library", 1 1(3), 469-480 (1999)

"High-throughput 1H NMR and HPLC characterization of a 96-member substituted methylene malonamic acid library", Hamper, Bruce C.; Snyderman, David M.; Owen, Thomas l; Scates, Angela M.; Owsley, Dennis C.; Kesselring, Allen S.; Chott, Robert C., J. Combi. Chem., 2, 140, (1999)